Guidance Agenda:
Guidances CDER is Planning to Develop During Calendar Year 2006

(See the Good Guidance Practices (GGPs) regulation on this Web page or 21 CFR 10.115 for details about the Guidance Agenda.)

CATEGORY — Advertising

- Presentation of Risk Information in Prescription Drug and Medical Device

CATEGORY — Chemistry

- Immunogenicity Assessment for Follow-on Protein products
- Immunogenicity Assessment for Therapeutic Protein Products
- Individual Product Bioequivalence Recommendations
- Patient Specific Drug Products
- Quality by Design
- Recommendations for Determination of Bioequivalence of Vaginal Antifungal Products
- Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes

CATEGORY — Clinical/Medical

- Androgens in Aging Males
- Clinical Development of Drugs for Irritable Bowel Syndrome
- Clinical Evaluation of Agents to Lower the Risk of Developing Sporadic Colorectal Adenomas
- Clinical Evaluation of Drugs for Female Infertility
- Clinical Evaluation of Drug Products for Inflammatory Bowel Disease
- Clinical Trial Design for the Treatment of Bacterial Blepharitis
- Clinical Trial Design for the Treatment of Bacterial Conjunctivitis
- Clinical Trial Design for the Treatment of Bacterial Corneal Ulcers
- Clinical Trial Design for the Treatment of Dry Eye
- Clinical Trial Design for the Treatment of Superficial Punctate Keratitis (SPK)
- Conducting and Submitting Virology Studies to the Division of Antiviral Drug Products
- Co-packaged Sodium Nitrite and Sodium Thiosulfate Drug Products – Submitting a New Drug Application
- Developing Analgesic Products for the Treatment of Pain
- Developing Drugs to Treat or Prevent Smallpox (Variola) Injection
- Development of Drugs for Chronic Obstructive Pulmonary Disease (COPD)
- Drug Development for the Treatment of Malaria
- Evaluation of New Treatments for Diabetes Mellitus
- Inhalational Anthrax (Symptomatic) - Developing Therapeutic Agents that Target Anthrax Toxin
- Obesity and Weight Loss
- Oral Mucositis
- Patient Reported Outcomes (PRO) Measures
- Periodontitis
- Peripheral Neuropathy
- Treatment of Congestive Heart Failure

CATEGORY — Clinical/Pharmacology

- Immediate Release to Modified Release Dosage Forms
- In Vitro Drug Metabolism/Drug Interaction – Guidance for Reviewers

CATEGORY — Combination Products

- Drug Diagnostic Co-Development

CATEGORY — Compliance

- Maintaining Adequate and Accurate Records During Clinical Investigations
- Registration Requirements Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- Process Validation: General Principles and Practices
- Penicillin as Defined in the CGMP Regulation under 21 CFR 211 and Separation Requirements for Manufacturing
- Non-Penicillin Beta-Lactam Contamination
- Importation of Active Pharmaceutical Ingredients

CATEGORY — Drug Safety Information

- Good Naming, Labeling and Packaging (GNLP) Practices
- Pre-Marketing Evaluation of Drug-Induced Liver Injury
- Risk Management of Highly Suspect or Known Human Teratogens: Pregnancy Prevention Strategies
- Selecting and Submitting Proprietary Names for Evaluation

CATEGORY — Electronic Submissions

- Providing Regulatory Submissions in Electronic Format – Analysis Datasets and Documentation

CATEGORY — Good Review Practices

- Good Review Management Practices for INDs

CATEGORY — IND

- Consumer Product Safety Commission – Tamper Resistant Packaging for INDs
- Guidance for Clinical Investigators: Preparing and Submitting an Investigational New Drug Application

CATEGORY — Labeling

- Content and Format of the Clinical Pharmacology Section
- Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products – Content and Format
- Drug Names and Dosage Forms
- Indication and Usage Section of Labeling for Human Prescription Drugs and Biological Products – Content and Format
- Labeling Dietary Supplements for Women Who Are or Could Be Pregnant
- Labeling for Human Prescription Drug and Biologic Products – Pharmacologic Classification for the Highlights Section of Labeling
- Labeling for Outcome Claims for Drugs to Treat Hypertension
- Pregnancy Labeling Revisions
- Use of Pharmacologic/Therapeutic Classification in Approved Labeling

CATEGORY — OTC

- Actual Use Trials
- Labeling Comprehension Studies for OTC Drug Products
- Labeling of Skin Protectants
- Topical Drug Products for Vaginal Yeast Infections

CATEGORY — Pharmacology/Toxicology

- Nonclinical Safety Evaluation of Reformulated Drug Products, Including Administration by an Alternate Route
- Nonclinical Studies for Anticancer Drugs

CATEGORY — Procedural

- Assessment of Abuse Potential of Drugs
- Clinical Source Data
- Determining Whether Human Research with a Radioactive Drug can be Conducted Under a Radioactive Drug Research Committee
- Good Meeting Management Guidance
- Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals
- Process for Contracts and Written Requests Under the Best Pharmaceutical for Children Act
- Qualifying for Pediatric Exclusivity Under Section 505a of the Federal Food, Drug, and Cosmetic Act
- Target Product Profile – A Strategic Development Process Tool

Note: Agenda items reflect guidances under development as of the date of this posting.